



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0332]

Endotoxin Testing Recommendations for Single-Use Intraocular Ophthalmic Devices; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Endotoxin Testing Recommendations for Single-Use Intraocular Ophthalmic Devices." National outbreaks of Toxic Anterior Segment Syndrome (TASS) have been associated with single-use intraocular ophthalmic devices (IODs) and single-use intraocular ophthalmic surgical instruments/accessories that are contaminated with endotoxins. These devices can become contaminated as part of the manufacturing, sterilization, or packaging processes. This guidance document provides recommendations for endotoxin limits as well as endotoxin testing to manufacturers and other entities involved in submitting premarket applications (PMAs) or premarket notification submissions (510(k)s) for different categories of IODs to mitigate future outbreaks of TASS.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled "Endotoxin Testing Recommendations for Single-Use Intraocular Ophthalmic Devices" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Michelle Tarver, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 2504, Silver Spring, MD 20993-0002, 301-796-5620.

SUPPLEMENTARY INFORMATION:

I. Background

TASS has been increasing in frequency over the past decade from approximately 1 in 1,000 to about 2 in 100. Some cases of TASS are severe enough to require secondary surgical interventions including glaucoma surgery and corneal transplantation. The use of inadequately or improperly processed ophthalmic surgical instruments is one of many factors suggested as a potential cause of TASS. In many TASS cases, bacterial endotoxin from medical devices is believed to cause the inflammation.

This guidance document was developed to notify manufacturers and other entities involved in submitting PMAs or 510(k)s for different categories of IODs of the recommended endotoxin limit for the release of IODs and single-use intraocular ophthalmic surgical instruments/accessories in an effort to mitigate future TASS outbreaks.

The draft of this guidance was made available in the **Federal Register** on April 17, 2014 (79 FR 21777), and the comment period closed July 16, 2014. Only two sets of comments were received. The comments were minor, and FDA made revisions to the document in response to the comments where appropriate. FDA also removed posterior segment devices from the scope of the guidance document. FDA may address endotoxin testing recommendations for this device type in future guidance documents.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on endotoxin testing and limits for single-use IODs. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. Persons unable to download an electronic copy of "Endotoxin Testing Recommendations for Single-Use

Intraocular Ophthalmic Devices" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1836 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 814 have been approved under OMB control number 0910-0231.

V. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: August 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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